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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,116	01/24/2002	Todd K. Whitehurst	AB-165U	1864

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EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,116	WHITEHURST ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *12-14 and 23-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/31, 5/27, 7/7/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-22, drawn to a method for treating a patient with chronic pain, classified in class 607, subclass 046.

   II. Claims 23-26, drawn to an electrical therapeutic system, classified in class 607, subclass 002.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to alleviate urinary incontinence, invoke motor muscles for walking, or manipulate finger movement in patients with arthritis.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention: the species involving a leadless stimulator and the species involving a stimulator with leads.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with Laura Haburay Bishop on June 15, 2004 a provisional election was made with traverse to prosecute the invention of Group I and subsequently the species involving the use of a leadless stimulator, claims 1-11 and 15-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-14 and 23-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

7. The drawings are objected to because the non-descript boxes of Fig. 5 must be appropriately labeled with text. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of

an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The disclosure is objected to because of the following informalities: the status of the application referred to on page 11 must be updated.

Appropriate correction is required.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-11 and 15-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16, 18 and 19

of U.S. Patent No. 6,735,475. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the current application is not restricted to the *treatment* of chronic pain *per se* since the body of the claim does not breathe life and vitality into the claim preamble. The body of the claim merely requires that the stimulator be implanted adjacent to at least one peripheral nerve at least in part responsible for sensations in a region experiencing chronic pain. Nerves by nature are responsible for sensations. In the case of fibromyalgia, practically every sensation producing nerve in the body can be said to be in a region experiencing chronic pain. Furthermore, since headaches (or facial pain) can be chronic, a person employing the method defined by the '475 patent to treat such a headache (or facial pain) would necessarily be treating chronic pain. Once the applicant has received a patent on a more specific embodiment he is not entitled to a patent for the generic or broader invention (See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)). In addition, the specific nerve structures claimed in the '475 patent include peripheral nerves as indicated by patented claim 3 (compare with claim 4 of the present application). Therefore if identical nerves are stimulated by identical pulses (note claims 2 and 3 as compared to patented claims 4 and 5), the patented method would inherently treat chronic pain. Similar comments apply to independent claim 15 as compared to patented claim 11.

Claims 1-11 and 15-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 8, 14-16 and 22-31 of copending Application No. 10/081,820. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claim sets is that the '820 claims refer to implanting a stimulator of a size and shape suitable for placement adjacent to the vagus nerve, adjacent to at least one portion of the vagus nerve. Since the applicant has defined the term "adjacent" to connote "...as close as reasonably possible to targeted tissue, including touching or even being positioned within the tissue, but in general, may be as far as about 150 mm from the target tissue," any placement of the stimulator within a radius of 150 mm from the vagus nerve (or placed halfway between nerves located 300

mm apart) would be covered by the '820 patent (the examiner notes that while the claims are directed to leadless stimulators, the above definition does not distinguish between stimulators with leads and those without, and the phrase "...close as reasonably possible..." can include positions not touching or within the nerve tissue, but located some distance away). The examiner also considers a stimulator that is of a size and shape to be suitable for placement adjacent to a vagus nerve, to be of a size and shape suitable for placement adjacent a peripheral nerve.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-11 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (Pat. No. 6,185,452).

Regarding claim 1, although Schulman does not explicitly discuss a method for treating *chronic* pain, the body of the claim does not give life, vitality and meaning to the preamble and thus is not limited to methods for treating chronic pain. Claim 1 only requires that the stimulator be implanted in a region experiencing chronic pain (i.e., treatment of chronic pain itself is not required). Schulman discloses providing at least one leadless stimulator (100) having at least two electrodes (112a and 112b), implanting the at least one stimulator adjacent to (note the discussion above concerning the meaning of the word "adjacent") at least one nerve (see col. 2, lines 16-23), at least in part responsible for sensations in a region experiencing pain (note col. 3, lines 30-34); providing operating power to the at least one stimulator (see text abridging cols. 3 and 4), using at least one external appliance to transmit stimulation parameters to the at

least one stimulator (col. 5, lines 5-8), receiving and storing the stimulation parameters (col. 5, lines 5-28), generating stimulation pulses in accordance with the stimulation parameters (col. 5, lines 1-4), and delivering the stimulation pulses to nerves adjacent to the at least one stimulator (see col. 6, lines 59-63), wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve (see col. 6, lines 55-57).

Regarding the limitation concerning peripheral nerves, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation. If the patient were experiencing chronic pain all over, such as might be the case with a fibromyalsia patient, any nerve stimulator placed in the body –regardless of its intended use—could be said to be placed in a region experiencing chronic pain.

Regarding claims 2 and 3 and claims with similar limitations, note the pulse parameters listed in Table I (col. 7).

Regarding claim 4 and claims directed to specific nerves or chronic pain locations, as reasoned above, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation.

Regarding claim 9 and claims directed to details of the sensor, note the text abridging cols. 7 and 8.

In regards to claim 10 and similarly worded claims, Schulman shows in Fig. 2 a diagram of the stimulator containing a sensor 188 coupled to the stimulation electrodes.

Regarding claim 15, comments paralleling those made in the rejection of claim 1 apply here as well.

Concerning claim 21, note the text abridging cols. 7 and 8.

Regarding claim 22, Schulman disclose that glucose –a blood borne substance— may be sensed (text abridging cols. 7 and 8).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
June 15, 2004

KENNEDY SCHAETZLE
PRIMARY EXAMINER